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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,865

09/13/2006

Chul-Hwan KIM

4820-021

1520

83219

7590

09/09/2010

HOSOON LEE

9600 SW OAK ST. SUITE 525

TIGARD, OR 97223

EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

09/09/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,865	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> Benjamin Packard	<b>Art Unit</b> 1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' arguments, filed 6/30/10, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

**Claims 1, 2, and 4-14** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ha et al (KR 110150271) in view of Protniuk et al (J of Pharm Sci, Vol 91, No 1, (2002) 111-116).

Applicants assert Ha does not disclose stabilization of epigallocatechin gallate (EGCG) in water phase or a hydrophilic solvent, but merely teaches a solidified chitosan microsphere and a process for making the same. Further, Applicants assert the amount of chitosan added in Ha is more than desired to stabilize the EGCG, where the amount of stabilizer should be less than the amount of EGCG. Applicants assert Ha does not disclose a composition where the solvent is water, hexane, and a sorbitol compound, but instead is used only to form chitosan powders. Finally, Applicants assert the Examiner did not address the method steps of claim 8, which are directed to a water-in-stable composition and not a composition for further use in making solid microspheres.

Examiner disagrees. First, Examiner notes a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

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art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the composition of Ha et al, while eventually used to make a solidified chitosan microsphere, has an intermediate which is an emulsion with all the instantly claimed components. The fact that the composition is further processed does not negate the fact that the liquid composition is disclosed as an intermediate and obviousness can be found where the liquid composition reads on the instant claims. Examiner notes Applicants also claim where the composition is solidified by spray drying or lyophilization (see instant claim 3).

Second, Ha results in a composition of 2g EGCG with 20g chitosan and 5g of sorbitol, which results in a component ratio of 1:12.5. The total percent by weight of each component would be about 0.2% EGCG, 2% chitosan, and 0.5% sorbitol. Applicants' arguments with regards to this ratio providing stabilization are not well taken, as the instant claims allow 0.1-25.0% by weight of EGCG and 0.1-5.0% by weight the mixture of polymers. The claims range results in a ratio of EGCG to polymer mixture of 1:50 to 1:0.2. As such, the ratio disclosed in the prior art falls within the claimed range and as discussed above, the ability to stabilize EGCG is simply an intended use and not given patentable weight.

Finally, Examiner noted on pg 6 of the Office Action dated 03/31/2010 that the disclosure of Ha suggested the order of combination did not effect the end product, given all components are combined and then mixed in solution for an extended period, therefore the combination of all the components would be obvious, regardless the order

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combined. No evidence has been presented which suggests changing the order makes the composition unsuitable for microspheres after drying.

**Claim 3** stands rejected under 35 U.S.C. 103(a) as being unpatentable over Ha et al (KR 110150271) in view of Protniuk et al (J of Pharm Sci, Vol 91, No 1, (2002) 111-116), the combination further in view of Morre et al (US 6,410,052).

Applicants assert that as claim 1 should be allowable, the remaining claims likewise should be allowable.

Examiner disagrees. As discussed above, Ha et al in view of Protniuk et al makes obvious the composition instantly claimed, therefore this rejection is maintained.

### ***Conclusion***

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612